

## **REMARKS**

### **STATUS OF THE CASE**

Upon entry of this amendment, Claims 55, 59, and 62-64 are pending in the application. Claims 1-54 have been previously cancelled. Claims 56-58, 60-61, and 65-69 are now cancelled, without prejudice, to expedite prosecution. Claims 55, 59, and 62-64 are amended herein. Support for the present amendments is found throughout the originally filed specification and claims. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

### **APPLICANTS' CLAIMS COMPLY WITH 35 U.S.C. §112 1<sup>ST</sup> PARAGRAPH**

In the August 29, 2008 Office Action ("Action"), Claims 55-69 stand rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the enablement requirement. The claims were alleged to contain subject matter that is not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Applicants respectfully traverse this rejection.

Applicants have amended independent Claims 55 and 62 to focus on a method of treating the recited specific cancers using a specific cyclic peptide, dolastatin 11. Support for the present amendments can be found throughout the specification, *inter alia*, at pages 30-32.

Applicants respectfully submit that the rejection of Claims 55-69 detailed in the Action is rendered moot in light of the present amendments. All allegations of non-enablement of the rejected claims are focused on compositions comprising nucleic acids of a

zyxin gene, fragments thereof and complementary sequences. For example, the Office Action asserts:

Therefore, one cannot extrapolate the teachings of the specification to the scope of the claims because the claims are drawn to a pharmaceutical composition comprising a nucleic acid molecule comprising cDNA of a zyxin gene, a fragment thereof or a complementary sequence, and applicant has not enabled the pharmaceutical composition because it has not been shown that these polynucleotides are capable of functioning as to that which is being disclosed.

(Action at pages 6-7). While not acquiescing to the Action's analysis, all references to the allegedly non-enabled subject matter have been eliminated from the current claims. Applicants submit that the amendments to the claims obviate the Examiner's concerns.

Furthermore, Applicants have now focused the claims on a specific well-characterized compound for a specific well-supported utility. The claims focus on preferred embodiments comprising the cyclic peptide dolastatin 11. Specifically, dolastatin 11 is also demonstrated to have efficacy against tumors *in-vivo*, said tumors having an EWS proto-oncogene which is present in the chromosomal translocation of band q12 of the reworked chromosome 22 with band q24 of chromosome 11 as found in Ewing's sarcoma and malignant melanoma (the cancers recited in Claims 63 and 64). See the *in-vivo* experiments using dolastatin 11 described on pages 30-32. The Applicants respectfully submit that the amended Claims 55, 59, 62 and 64 are thus fully enabled by the specification as originally filed.

Accordingly, Applicants respectfully request the Examiner to reconsider and withdraw the present rejection of Claims 55, 59, 62 and 64 under 35 U.S.C. §112, first paragraph.

## CONCLUSION

Applicants submit that the claimed methods of treatment are not unduly broad – they are focused on the treatment of specific cancers associated with chromosomal anomalies of region of 7q34/q35 of zyxin gene with a specific compound, dolastatin 11. (Claims 63 and 64 are even further focused on treatment of the Ewing's sarcoma and melanoma.) Accordingly, Applicants submit that the claims are fully enabled, and request withdrawal of the rejections under 38 U.S.C. §112.

It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: February 27, 2009

By: 

David L. Suter, Reg. No. 30,692  
Fernando Alberdi, Ph.D., Reg. No. 62,688

HARNESS, DICKEY & PIERCE, P.L.C.  
P.O. Box 828  
Bloomfield Hills, Michigan 48303  
(248) 641-1600

DLS/FEA/akb/kq